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10/718,398

11/19/2003

Fredericus Antonius Dijcks

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08/25/2006

AKZO NOBEL INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/718,398

Applicant(s)

DIJCKS ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/28/2006 & 8/10/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/19/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

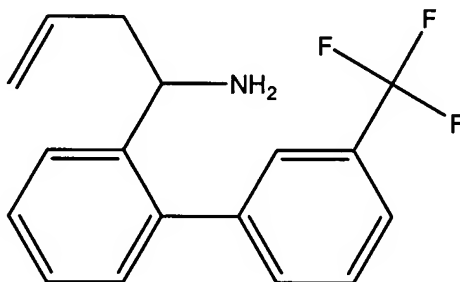
Art Unit: 1626

**DETAILED ACTION**

Claims 23-26 are pending in the application.

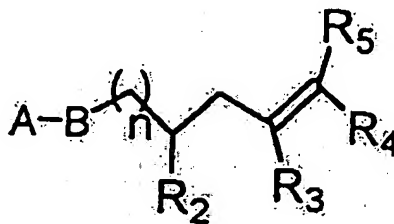
***Election/Restrictions***

Applicants' election with traverse of the species



2-(3-trifluoromethylphenyl)-alpha-2-propenyl-benzenemethanamine

compound (34) found on page 90 of the instant specification in the reply filed on April 28, 2006 and August 10, 2006 is acknowledged. The elected species is embraced by formula I (reproduced below), starting on page 58, last line,



(I)

Art Unit: 1626

wherein A is (a); Y is CH; X is CH=CH; P and S are each hydrogen; R<sub>1</sub> is on ring (a) is trifluoromethyl; B is (d); R<sup>1</sup> on ring (d) is hydrogen; R<sub>2</sub> is NH<sub>2</sub>; n is zero; and R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> each represent hydrogen.

The traversal is on the ground(s) that: (1) they are entitled to proceed with substantive examination of claim 23 having broad coverage, since Applicants allege that the instant claimed methods of using I<sub>h</sub> channel inhibitors is novel; (2) broad terms encompassing various compounds in which terms describe the compounds by their mechanism of action or their binding to a particular receptor have been allowed by the U.S. Patent Office; (3) the different specie described in the specification all possess the same property and also share the same utility; and (4) the Examiner has failed to show that there would be a serious burden.

All of Applicants' arguments have been considered but have not been found persuasive. Applicants are claiming a method for treating a psychiatric disorder

Art Unit: 1626

by administering a  $I_h$  channel inhibitor. The claims do not recite a disclosed and defined genus of compounds of any formula or a disclosed species. The structure of a compound that would meet the instant claims would vary in structure and element and would be patentably distinct. The required searches would encompass many classes and subclasses as well as a multitude of database searches. Therefore, it would be impose an undue burden on the Examiner and the Patent Office's resources if an election of species were not required.

Applicants' argue that broad terms encompassing various compounds in which terms describe the compounds by their mechanism of action or their binding to a particular receptor have been allowed by the U.S. Patent Office. In response, the allowance of claims by the U.S. Patent Office has no relevancy in the consideration of the question of patentability of claims in another case. In re Greider et al., 54 USPQ 139.

Art Unit: 1626

The requirement is still deemed proper and is therefore made FINAL.

The instant application has been examined according to M.P.E.P. 803.02. Since no prior art was found on the elected species for the instant claimed method of use, the search of the instant claimed invention was expanded until prior art was found. The search was then stopped and the prior art applied.

Claimed subject matter not embraced by the below applied prior art is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 28, 2006 and August 10, 2006.

Art Unit: 1626

### ***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statement filed on November 19, 2003.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

Art Unit: 1626

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,313,139 and claims 7 and 8 of U.S. Patent No. 6,080,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the instant method of use embraces all compounds that are  $I_h$  channel inhibitors and that have a  $pIC_{50}$  of 5 to 12, the compounds being administered for treating psychiatric disorders in each of the patents are embraced by the instant claimed invention.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar



Art Unit: 1626

compounds would possess similar activity (e.g., treating a psychiatric disorder).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating psychiatric disorders. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds disclosed by the instant

Art Unit: 1626

specification for treating a psychiatric disorder by administering an  $I_h$  channel inhibitor having a  $pIC_{50}$  of 5 to 12 for inhibition of the hyperpolarization-activated cation current in dorsal root ganglion cells, does not reasonably provide enablement for any compound presently known or will become known in the future which is an  $I_h$  channel inhibitor having a  $pIC_{50}$  of 5 to 12 for inhibition of the hyperpolarization-activated cation current in dorsal root ganglion cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,

Art Unit: 1626

3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

***The nature of the invention***

Applicants are claiming methods for treating a psychiatric disorder by administering an effective amount of an  $I_h$  channel inhibitor which has a  $pIC_{50}$  of 5 to 12 for inhibition of the hyperpolarization-activated cation current in dorsal root ganglion cells. See, for example, instant claim 23. The instant claims do not recite a disclosed genus of any formula to represent an  $I_h$  channel inhibitor or any particular disclosed specie which represents an  $I_h$  channel inhibitor. From the reading of the specification, it appears that Applicants are asserting that any compound, because of

Art Unit: 1626

its mode action, which involves being a  $I_h$  channel modulator, would be useful for treating all psychiatric disorders.

***The amount of direction or guidance present and the presence or absence of working examples***

That a single class of compounds {i.e., an  $I_h$  channel inhibitor} can be used to treat all psychiatric disorders embraced by the claims is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all psychiatric disorders by administering the any compound that can be classified as an  $I_h$  channel inhibitor.

***The breadth of the claims***

The breadth of the claims is treating all psychiatric disorders generically embraced in the claim language by administering any  $I_h$  channel inhibitor which

has a  $\text{pIC}_{50}$  of 5 to 12 for inhibition of the hyperpolarization-activated cation current in dorsal root ganglion cells.

***The quantity of experimentation needed***

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all psychiatric disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

Art Unit: 1626

***The level of the skill in the art***

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-26 are indefinite because the metes and bounds of these claims cannot be ascertained since a compound that meets the definition of a Ih channel inhibitor is not recited in the instant claims.

Art Unit: 1626

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Morad et al. {U.S. Pat. 4,894,376}

Morad et al. disclose the compounds in column 4, lines 57-63, which are useful for treating psychiatric disorders such as manic depressive illness (column 3, lines 30-68; column 4, lines 1-15; and columns 6-7).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morad et al. {U.S. Pat. 4,894,376}.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim a method for treating a psychiatric disorder by administering an effective amount of an I<sub>h</sub> inhibitor. Morad et al. teach methods of treating diseases characterized by hyperexcitability of neurons. Morad teach that psychiatric disorders, such as manic depressive illness, can be treated by administering a substituted pyrazinoylguanidine, such



Art Unit: 1626

as amiloride (see entire document, especially column 3, lines 30-68; column 4, lines 1-15 and 57-63; and columns 6-7).

***Ascertainment of the difference between the prior art and the claims  
(MPEP §2141.02)***

The difference, if any, is the recitation of a particular  $IC_{50}$  range as recited in the instant claimed invention.

***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the compounds of the prior art derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating psychiatric disorders).

One skilled in the art would thus be motivated to administer products embraced by the prior art to arrive

Art Unit: 1626

at the instant claimed invention with the expectation of treating psychiatric disorders. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

The method of using the elected species of compound (34) found on page 90 of the instant specification for the purposes of the instant claimed invention is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

August 21, 2006